

REMARKS

Status of the Claims

Claims 1-11 and 14 are currently pending in the application. Claims 1-6, 9 and 10 stand rejected. Claims 7, 8, 11 and 14 are withdrawn as being drawn to a non-elected invention. Claims 1 has been amended as set forth herein without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by the specification at, for instance, Figure 1 and pages 11-15. Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 102(a)

Claims 1, 5, 9 and 10 stand rejected under 35 U.S.C. § 102(a) as being anticipated in light of Lumelsky et al., *Science*, 292:1389-1394, 2001 (hereinafter "Lumelsky et al."). (See, Office Action of January 22, 2007, at pages 2-5). Applicants traverse the rejection as set forth herein.

The Examiner states that Lumelsky et al. disclose the use of LIF in the medium in which ES cells are grown (Figure 1) and that expansion of EB's is performed in the presence of bFGF. The Examiner further states that the order in which steps are performed cannot be the basis of distinguishing the presently claimed invention over the cited reference.

However, Part A of Figure 1 of Lumelsky et al. discloses Stage 1 as being an expansion of ES cells and uses LIF. Figure 1 of Lumelsky et al. also shows that in Stage 2 formation of EBs does not include LIF. According to this same Figure 1, bFGF is used at Stage 4, the stage of expansion of pancreatic endocrine progenitor cells, of the method disclosed in Lumelsky et al. Thus, the differences between the method of Lumelsky et al. and the presently claimed method

are readily apparent by simply comparing Figure 1 of Lumelsky et al. with the presently claimed invention, as reflected, for instance, in Figure 1 and pages 11-15 of the present specification and presently amended claim 1.

That is, as reflected in Figure 1 of the present invention, and amended claim 1, Applicants' method is directed to four steps, performed in order, from (A) to (D). These four steps are approximate to the 5 stages reflected in Figure 1 of Lumelsky et al. However, there are material distinguishing features between the two methods, as already discussed in Applicants' prior reply and as reflected herein. That is, Stage 2 of Lumelsky et al. clearly does require an absence of LIF whereas the presently claimed invention includes LIF in approximately corresponding step (B). This difference, and other differences, achieve the method of the presently claimed invention. Furthermore, step (B) of the presently claimed method according to claim 1 also requires the presence of bFGF, whereas in contrast Lumelsky et al. requires bFGF only at Stage 4.

Although Applicants do not agree that the claims are anticipated by the disclosure of Lumelsky et al., to expedite prosecution, claim 1 has been amended herein, without prejudice or disclaimer, to recite, in part, "A method for inducing differentiation of mammalian embryonic stem cells into insulin-producing cells, which comprises performing the following steps, in order from (A) to (D) as follows. . ." Additional amendments are made to the various steps of claim 1 to more clearly reflect that which Applicants intend to encompass by the claimed method. These amendments clearly distinguish the presently claimed method over that disclosed by Lumelsky et al. for the reasons set forth above, as reflected in Figure 1 of Lumelsky et al. Support for these amendments may be found at, for instance, Figure 1 and pages 11-15 of the specification.

Therefore, Lumelsky et al. cannot anticipate the presently claimed invention because Lumelsky et al. do not disclose all of the limitations of the presently claimed invention, especially as recited in amended claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (See, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)).

Dependent claims 5, 9 and 10 are not anticipated as, *inter alia*, depending either directly or indirectly from a non-anticipated base claim, amended claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1, 5, 9 and 10 are respectfully requested.

Rejections Under 35 U.S.C. § 102(e)

Claims 1-6, 9 and 10 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Lumelsky et al., U.S. Patent Application Publication No. 2004/0121460 (hereinafter referred to as "Lumelsky II"). (See, Office Action, at pages 5-6). Applicants traverse the rejection as set forth herein.

The Examiner's comments concerning Lumelsky II are similar to the points and reasoning provided for the basis of the rejection under 35 U.S.C. § 102(a) in light of Lumelsky et al., above. Therefore, Applicants believe that the comments and reasoning provided above, with respect to amended claim 1 and the anticipation rejection over Lumelsky et al., also sufficiently address the present rejection under 35 U.S.C. § 102(e). That is, the presently claimed invention

is clearly distinguishable from the invention of Lumelsky II based on the material differences provided in the steps of presently amended claim 1.

Therefore, Lumelsky II cannot anticipate the presently claimed invention because Lumelsky II do not disclose all of the limitations of the presently claimed invention, especially as recited in amended claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (See, *Verdegaal Bros*, 814 F.2d at 631, 2 U.S.P.Q.2d at 1053).

Dependent claims 2-6, 9 and 10 are not anticipated as, *inter alia*, depending either directly or indirectly from a non-anticipated base claim, claim 1.

Reconsideration and withdrawal of the anticipation rejection of claims 1-6, 9 and 10 are respectfully requested.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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